N.E. On the last page of the application, please incorporate the enclosed Abstract.

IN THE CLAIMS:

1. (Amended) An immunoregulator obtainable from urine [capable of regulating] that regulates Th1, [and/or] Th2 or both Th1 and Th2 cell activity.

2. (Amended) An immunoregulator obtainable from urine [capable of modulating] that modulates dendritic cell differentiation.

3. (Amended) [An] The immunoregulator [according to] of claim 1 [capable of modulating] that modulates dendritic cell differentiation.

A3 cont

4. (Amended) [An] The immunoregulator [according to] of claim 3 wherein said urine is obtained from a pregnant mammal[, preferably wherein said mammal is human].

5. (Amended) An immunoregulator comprising an active component, or a functional fragment thereof, obtainable from a mammalian chorionic gonadotropin preparation, wherein said active component [capable of stimulating] stimulates splenocytes obtained from a non-obese diabetes (NOD) mouse[, or comprising an active component functionally related to said active compound].

6. (Amended) An immunoregulator comprising an active component obtainable from a mammalian chorionic gonadotropin preparation, wherein said active component [capable of protecting] protects a mouse against a lipopolysaccharide induced septic shock.

7. (Amended) [An] The immunoregulator [according to] of claim 5 [or 6] wherein said active component is present in a fraction which elutes with an [apparent] approximate molecular weight of [58 to 15 kilodalton] 15 to 58 kilodaltons as determined in gel-permeation chromatography.

8. (Amended) [An] The immunoregulator [according to] of claim 5 [or 6] wherein said active component is present in a fraction which elutes with an [apparent] approximate molecular weight of [15 to 1 kilodalton] 1 to 15 kilodaltons as determined in gel-permeation chromatography.

9. (Amended) [An] The immunoregulator [according to] of claim 5 [or 6] wherein said active component is present in a fraction which elutes with an [apparent] approximate molecular weight of [< 1] less than one kilodaton as determined in gel-permeation chromatography.

10. (Amended) [An] The immunoregulator [according to] of claim [7, 8 or] 9 wherein said mammalian chorionic gonadotropin preparation is derived from urine.

A3 cont

11. (Amended) [An] The immunoregulator [according to anyone of claims 5 to] of claim 10 [capable of regulating] that regulates Th1, [and/or] Th2 or both Th1 and Th2 cell activity.

12. (Amended) [An] The immunoregulator [according to anyone of claims 5 to] of claim 11[capable of modulating] that modulates dendritic cell differentiation.

13. (Amended) [An] The immunoregulator [according to anyone of claims 5 to] of claim 12 wherein said stimulated splenocytes [are capable delaying] delay the onset of diabetes in a NOD-severe-combined immunodeficient mouse reconstituted with said splenocytes.

14. (Amended) [An] The immunoregulator [according to anyone of claims 5 to] of claim 13 wherein said active component [is capable of inhibiting] inhibits gamma-interferon production of splenocytes obtained from a non-obese diabetes (NOD) mouse.

15. (Amended) [An] The immunoregulator [according to anyone of claims 5 to] of claim 14 wherein said active component [is capable of stimulating] stimulates [interleukine-4]interleukin-4 production of splenocytes obtained from a non-obese diabetes (NOD) mouse.

16. (Amended) [An] The immunoregulator [according to anyone of claims 5 to] of claim 15 wherein said active component [is capable of reducing] reduces ASAT plasma levels after or during organ failure.

17. (Amended) [Use of an] A method of treating an immune-related disorder in a subject believed to be in need thereof, said method comprising:

administering to the subject an amount of an immunoregulator [according to anyone of claims 1 to 16 for the production of a pharmaceutical composition for the treatment of an immune-mediated-disorder] obtainable from mammalian urine, wherein said immunoregulator modulates Th1, Th2 or both Th1 and Th2 cell activity and is administered in an amount sufficient to modulate the immune-related disorder.

18. (Amended) [Use] The method according to claim 17 wherein said immune-mediated disorder [comprises]is selected from the group consisting of chronic inflammation, [such as] diabetes, multiple sclerosis [or], and chronic transplant rejection.

19. (Amended) [Use] The method according to claim 17 wherein said immune-mediated disorder [comprises]is selected from the group consisting of acute inflammation, [such as] septic shock, [or] anaphylactic shock [or], and acute or hyper acute transplant rejection.

20. (Amended) [Use] The method according to claim 17 wherein said immune-mediated disorder [comprises]is selected from the group consisting of auto-immune disease, [such as] systemic lupus erythematosus[or], and rheumatoid arthritis.

21. (Amended) [Use] The method according to claim 17 wherein said immune-mediated disorder [comprises]is selected from the group consisting of allergy, [such as] asthma [or]and parasitic disease.

22. (Amended) [Use] The method according to claim 17 wherein said immune-mediated disorder [comprises]is selected from the group consisting of an overly strong immune response directed against an infectious agent, [such as] a virus [or]and bacterium.

23. (Amended) [Use] The method according to claim 17 [to 22] wherein said treatment comprises regulating relative ratios, [and/or] cytokine activity or both relative ratios and cytokine activity of lymphocyte subset-populations in a treated individual.

24. (Amended) [Use] The method according to claim 23 wherein said subset populations comprise Th1 or Th2 cells.

25. (Amended) [Use] The method according to [anyone of claims] claim 17 [to 24] wherein said immunoregulator comprises [a] an hCG preparation or a fraction derived thereof.

26. (Amended) A pharmaceutical composition for [treating an immune-mediated disorder] comprising an active component, or derivative thereof, obtainable from urine [capable of stimulating] that stimulates splenocytes obtained from a non-obese diabetes (NOD) mouse, said stimulated splenocytes delaying the onset of diabetes in a NOD-severe-combined-immunodeficient mouse reconstituted with said splenocytes[, or comprising an active component functionally related to said active component].

27. (Amended) [A] The pharmaceutical composition [for treating an immune-mediated disorder according to] of claim 26 wherein said active component [is capable of inhibiting] inhibits gamma-interferon production or stimulating interleukine-4 production of splenocytes obtained from non-obese diabetes (NOD) mouse.

29. (Amended) [A] The pharmaceutical composition [for treating an immune-mediated disorder according to anyone of[claims] of claim 26 [to 28 obtainable] obtained from a pregnant mammal[, preferably a human].

30. (Amended) [A] The pharmaceutical composition [for treating an immune-mediated disorder according to] of claim 29 comprising a clinical grade hCG preparation or a fraction derived thereof.

31. (Amended) A method for treating an immune-mediated disorder in a subject comprising: [subjecting an animal to treatment with] administering to the subject at least one immunoregulator [according to any one of claims 1 to 16] , said immunoregulator obtainable from mammalian urine, and having Th1 and Th2 cell regulating activity, said immunoregulator being administered in an amount sufficient to modulate dendritic cell differentiation.

32. (Amended) [A] The method according to claim 31 wherein said immune-mediated disorder [comprises]includes diabetes.

33. (Amended) [A] The method according to claim 32 wherein said immune-mediated disorder [comprises]includes sepsis.

34. (Amended) [A] The method according to [any one of claims] claim [31 to] 33 further comprising regulating relative ratios, [and/or] cytokine activity or both relative ratios and cytokine activity of lymphocyte subset-populations in said [animal]subject.

35. (Amended) [A] The method according to claim 34 wherein said subset-populations comprise Th1 or Th2 cells.

37. (Amended) A method for selecting an immunoregulator comprising determining therapeutic effect of an immunoregulator by subjecting an animal prone to show signs of septic shock to a urine fraction or fraction derived thereof, and determining the development of septic shock in said animal.

38. (Amended) [A] The method according to claim 36 [or 37] wherein said therapeutic effect is further measured by determining relative ratios, [and/or] cytokine activity or relative ratios and cytokine activity of lymphocyte subset-populations in said animal.

39. (Amended) [A] The method according to claim 38 wherein said therapeutic effect is further measured by determining enzyme levels in said animal.

Please cancel claims 40 through 42 without prejudice or disclaimer.

Please add the following claims:

43. The immunoregulator of claim 4 wherein said pregnant mammal is a human.

44. The immunoregulator of claim 6 wherein said active component is present in a fraction which elutes with an approximate molecular weight of 15 to 58 kilodaltons as determined in gel-permeation chromatography.

45. The immunoregulator of claim 44 wherein said mammalian chorionic gonadotropin preparation is derived from urine.

46. The immunoregulator of claim 6 that regulates Th1, Th2 or both Th1 and Th2 cell activity.

47. The immunoregulator of claim 6 that modulates dendritic cell differentiation.

48. The immunoregulator of claim 6 wherein said stimulated splenocytes delay the onset of diabetes in a NOD-severe-combined immunodeficient mouse reconstituted with said splenocytes.

49. The immunoregulator of claim 6 wherein said active component inhibits gamma-interferon production of splenocytes obtained from a non-obese diabetes (NOD) mouse.